

WORKING TO KEEP TOBACCO OUT OF THE HANDS OF OUR YOUTH

Tobacco products, including e-cigarettes, are creating dangerous health implications for Michigan's young people.

That's why the Keep MI Kids Tobacco Free Alliance, including nearly 70 organizations, is working together to strengthen Michigan's tobacco control laws.

Keep MI Kids Tobacco Free

ALLIANCE

Learn more about our efforts at keepmikidstobaccofree.com



The Dangers of Tobacco and E-Cigarettes

- Tobacco is the #1 preventable cause of death in Michigan and the U.S., killing 16,200 people in Michigan each year and more than 480,000 Americans nationwide. 1
- Nationally, e-cigarette use has increased 135 percent by high schoolers and over 200 percent by middle schoolers in the last two years alone, and currently 27.5 percent of high school students and 10.5 percent of middle school students use e-cigarettes.²
- Research shows that flavors play a key role in youth use o e-cigarettes. 97% of current youth e-cigarette users have used a flavored e-cigarette in the past month and 70% of current youth e-cigarette users say they use e-cigarettes "because they come in flavors I like."
- A study found that youth who use e-cigarettes are six times more likely to migrate to combustible tobacco use than youth who never tried e-cigarettes.⁴
- The U.S. Surgeon General and the FDA have declared youth e-cigarette use an epidemic.²
- Researchers have debunked the myth that e-cigarettes are 95 percent safer than cigarettes. An article published in the Americar Journal of Public Health called the estimate "a factoid" that was based on opinion, not scientific research.
- E-cigarettes have not been proven to be effective in smoking cessation.⁶
- The Surgeon General has concluded that youth use of nicotine in any form, including e-cigarettes, is unsafe and can harm brain development.⁷
- There is growing evidence that vaping can harm lung health and may increase the risk for more severe consequences from COVID-19.
 - 1 Campaign for Tobacco-Free Kids
 - 2. Center for Disease Control and Prevention
 - 3. Food and Drug Administration
 - 4. American Journal of Pediatrics
- 5, American Journal of Public Health
- 6. FDA Commissioner
- 7. U.S. Surgeon General
- B. Dr. Nora Volkow, National Institute on Drug Abuse

June 23, 2020

Representative Michael Webber Chair, House Regulatory Reform Committee

RE: Senate Bills 781-786

Dear Chairman Webber and committee members.



On behalf of the Keep MI Kids Tobacco Free Alliance, we would like to thank you for the opportunity to be part of the dialogue on reducing the youth e-cigarette epidemic. The Alliance includes nearly 70 public health and community organizations eager to work with lawmakers to pass comprehensive legislation proven to protect our youth. Tobacco products, including electronic cigarettes, continue to have a significant toll on Michigan. We all must do more.

During these uncertain times, it's easy to forget that we are still facing skyrocketing youth tobacco use and unacceptably high rates of adult tobacco use in Michigan. Data from FDA compliance inspections for the state reflect retail violation rates that are almost double the national average and Michigan has the highest number of 'no sale orders' nationwide for unlawful selling of tobacco and nicotine in retail outlets. Tobacco remains the number one cause of preventable death and disease worldwide and we feel it is critical to work to improve and ensure the health and safety of every Michigan resident through strong legislation.

Our Alliance worked with Senators to improve this package and while we appreciate the changes that have been made to strengthen this legislation to date, we believe more must be done. There is opportunity to further make these bills stronger and more effective to better protect our youth. We appreciate your consideration during today's hearing and hope to have discussions with committee members in the coming weeks on ways to improve this bill package. If the goal is truly to strengthen our tobacco laws and protect our youth, we believe more changes are needed to achieve those goals.

Additionally, we must address a dangerous mistruth that continues to circulate. There is no actual evidence that e-cigarettes are less harmful than combustible cigarettes, despite a debunked "study" from the United Kingdom. In January, the American Journal of Public Health officially refuted the now too often-repeated erroneous claim that e-cigarettes have been proven to be 95% safer than regular cigarettes. Even the Surgeon General, serving under President Trump, does not support this claim.

For that reason, we propose the following improvements to the bill package:

- Create parity in the tax rate on all tobacco products, including e-cigarettes. Equivalency will
 reduce "toggling, or dual use amongst products" in an effort to evade a higher-taxed product. Kids are
 MOST responsive to price, so the more cheaply priced, the greater the use rates amongst kids. The
 current language in SB 781 does not accomplish this.
- Strengthen enforcement among retailers selling tobacco products by requiring two compliance checks per year, which is a best practice across the country. We propose that the vehicle to fund enforcement of the law be sourced through a fee-based mechanism, as a cost of operations, a small price to pay given net profitability, and to ensure Michigan's kids are being protected. This law is only as strong as its ability to be enforced.
- Eliminate SB 783 as this bill is likely to provoke First Amendment, federal preemption, and void-forvagueness challenges. The bill also essentially would allow e-cigarettes of all flavors to be sold to anyone over 21, contradicting federal law.
- Clarify definitions of tobacco/nicotine to ensure that all products are treated with equivalency. Additionally, this clarification strengthens Michigan code by eliminating the need to revisit language when new products enter the market, creating a more efficient legislative process.

The Keep MI Kids Tobacco Free Alliance is willing to serve as a resource and provide language for amendments to the package. We look forward to partnering with you to protect all of Michigan's kids from the dangers of tobacco.

Sincerely,

Keep MI Kids Tobacco Free Alliance co-chairs

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Keep MI Kids Tobacco Free Alliance members

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- Alliance of Coalitions for Healthy Communities
- American Cancer Society Cancer Action Network
- American Heart Association
- American Indian Veterans of Michigan
- American Lung Association
- Arbor Circle
- Ascension Michigan
- Beaumont Teen Health Center
- BreatheWell Newaygo County
- Campaign for Tobacco-Free Kids
- CARE of Southeastern Michigan
- Cherry Health
- Community Mental Health Association of Michigan
- Genesee Health Plan
- Genesee County Medical Society
- Genesee County Prevention Coalition
- Henry Ford Health System
- Hurley Medical Center
- Ingham County Medical Society
- March of Dimes
- Mercy Health
- McLaren Health Care
- Michigan's Children
- Michigan Academy of Family Physicians
- Michigan Association of Local Public Health
- Michigan Black Caucus Foundation
- Michigan Catholic Conference
- Michigan Chapter of American Academy of Pediatrics

- Michigan Chapter of American College of Cardiology
- Michigan Council for Maternal and Child Health
- Michigan Council of Nurse Practitioners
- Michigan Health and Hospital Association
- Michigan League for Public Policy/Kids' Count
- Michigan Nurses Association
- Michigan Osteopathic Association
- Michigan Public Health Coalition
- Michigan Society of Hematology and Oncology
- Michigan State Medical Society
- Michigan State University College of Human Medicine
- Michigan State University Extension
- Michigan Thoracic Society
- Newaygo County Great Start Collaborative
- Parents Against Vaping
- Prevention Network Michigan
- Preventing Tobacco Addiction Foundation
- Sacred Heart Center
- Saint Joseph Mercy Health System
- School-Community Health Alliance of Michigan
- South Eastern Michigan Indians
- Spectrum Health
- Tobacco Free Michigan
- Trinity Health
- Washtenaw County Medical Society

Invalidity of an Oft-Cited Estimate of the Relative Harms of Electronic Cigarettes

In July 2013, a group of 12 experts in decision science, medicine, pharmacology, psychology, public health policy, and toxicology rated the relative harm of 12 nicotine-containing products by using 14 criteria addressing harms to self and others.1 The group concluded that combustible cigarettes were the most harmful and that electronic nicotine delivery systems (electronic cigarettes of e-cigarettes) were substantially less harmful than combustible cigarettes. These results have been characterized and repeated in the popular media as e-cigarettes are "95% less risky" or "95% less harmful" than combustible cigarettes. However, as the authors noted in a sweeping statement regarding the shortcomings of their own work, "A limitation of this study is the lack of hard evidence for the harms of most products on most of the criteria."1(p224)

Despite this lack of hard evidence, Public Health England and the Royal College of Physicians endorsed and publicized the "95% less harmful" assertion. ^{2,3} Senior Public Health England staff emphasized the "evidence" underlying the 95% figure, despite the evidence being lacking. Much has been written about the dubious validity of the "95% less harmful" estimate in 2014 to 2016, especially about the

paucity of research on the health effects of e-cigarettes available in 2013. After six years of e-cigarette-focused research, which has yielded a growing body of hard evidence regarding harm (see Appendix A, available as a supplement to the online version of this article at http://www.ajph. org, for a nonexhaustive list), the time has come to re-examine that estimate.

TODAY'S ELECTRONIC CIGARETTES ARE DIFFERENT

There is ample evidence that the range of e-cigarette products available today is very different from that in July 2013. The differences are such that, even if the 2013 estimate was valid then, it can no longer apply today. For example, in addition to using different materials and more numerous heating coils, many e-cigarettes today can attain power output that exceeds that of most over-the-counter 2013 models by 10 to 20 times (i.e., up to and sometimes exceeding 200 watts). Greater power increases the potential harms of e-cigarette use because more aerosol is produced that exposes users to increased levels of nicotine and other toxicants. It also increases bystander exposure to any harmful aerosol constituents

because users exhale more aerosol. In addition, greater power increases the potential for malfunction (e.g., the device exploding), which could harm users and bystanders.

Also, e-cigarette liquids have changed considerably from 2013, with widespread availability of thousands of flavors that use chemicals "generally recognized as safe" to eat but with unknown pulmonary toxicity. Perhaps the most striking change has been the pervasive marketing of liquids with protonated nicotine.4 Protonated nicotine ("nicotine salt") is made by adding an acid to free-base nicotine, thus introducing another potential toxicant that was rare in 2013. Relative to free-base nicotine, aerosolized protonated liquid is less aversive to inhale, allowing users to increase the nicotine concentration of the liquid and likely increase their own nicotine

dependence. Protonated nicotine e-cigarette liquids are available today in concentrations greater than 60 milligrams per milliliter, and these liquids have become very popular, sparking a "nicotine arms race."

ELECTRONIC CIGARETTES CAUSE HARM TO CELLS

There is ample evidence, unavailable in 2013, that e-cigarette aerosols contain toxicants and that these aerosols are harmful to living cells in vitro and in vivo. For example, thermal degradation of e-cigarette liquid constituents can produce volatile aldehydes, which, at concentrations generated by e-cigarettes, display a variety of cardiorespiratory toxic effects. E-cigarettes can produce carcinogenic furans in addition to other toxicants such as chloropropanols. Even at room temperature, e-cigarette liquids can be unstable, producing irritating acetal compounds carried over into the aerosol. Numerous studies demonstrate that cell function is compromised following exposure to e-cigarette

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aerosol. Similarly, animals that are exposed to e-cigarette aerosols show clear indication of adverse consequences, including in models related to cardiovascular disease.

ELECTRONIC CIGARETTES HARM USERS

Recent evidence reveals that e-cigarette users show evidence of harm. For example, in a sample of healthy young occasional cigarette smokers who used an e-cigarette with or without nicotine, airway epithelial injury was observed in both conditions, with the authors concluding, "Thus, [e-cigarette] aerosol constituents could injure the respiratory system or worsen preexisting lung disease through a variety of mechanisms."5(pL716) Consistent with this report, wheezing, a symptom of potential respiratory disease, has been associated with e-cigarette use. E-cigarette use increases heart rate, blood pressure, and platelet activation, and decreases flow-mediated dilation and heart rate variability, effects that are prognostic of long-term cardiovascular risk. Indeed, a preliminary report indicates that e-cigarette users may be at increased risk for myocardial infarction and coronary artery disease.

ELECTRONIC CIGARETTES INCREASE SMOKING RISK

Since 2013, numerous surveys have demonstrated that e-cigarette use is increasing among individuals who previously were naïve to nicotine and that these individuals are at increased risk for initiation of combustible cigarette smoking. As the US National Academies of

Sciences, Engineering, and Medicine concluded, "There is substantial evidence that [e-cigarette] use increases risk of ever using combustible tobacco cigarettes among youth and young adults." To the extent that initial e-cigarette use is a causal factor in subsequent combustible tobacco smoking for an individual who would have otherwise never initiated smoking, e-cigarette use could be considered to be as harmful as tobacco smoking for that individual.

ELECTRONIC CIGARETTE AEROSOL IS NOT HARMLESS

Differences in toxicant content between e-cigarette aerosol and cigarette smoke, by themselves, cannot convey lesser lethality because toxicity depends upon both the extent and mode of use. For example, propylene glycol (PG) is one of the primary constituents of e-cigarette aerosol and is generally recognized as safe when eaten but, when injected intravenously over a period of days, is toxic. E-cigarette aerosols containing propylene glycol and vegetable glycerin, another common constituent, cause inflammation in human lungs, suggesting differing safety profiles for inhaled versus ingested propylene glycol and vegetable glycerin. Furthermore, as the toxicants in e-cigarette aerosol sometimes differ from cigarette smoke, so might any resulting e-cigarette-caused disease states. There is little doubt that exclusive e-cigarette users are unlikely to die from lung cancer that is caused by carcinogenic tobacco-specific nitrosamines or polycyclic aromatic hydrocarbons, toxicants largely absent from e-cigarette aerosols. What diseases they may die

of—and if their deaths are hastened by their e-cigarette use will be part of the much-needed evidence base upon which valid risk estimates can be built.

CONCLUSIONS

In sum, a 2013 evidencelacking estimate of the harm of e-cigarettes relative to combustible cigarettes has been cited often. However, since 2013, e-cigarette devices and liquids have changed. Evidence of potential harm has accumulated. Therefore, the evidence-lacking estimate derived in 2013 cannot be valid today and should not be relied upon further. Future estimates of the harm of e-cigarettes should be based on the evidence that is now available and revised accordingly as more evidence accrues.

CALL TO ACTION

The "95% safer" estimate is a "factoid": unreliable information repeated so often that it becomes accepted as fact. Public health practitioners, scientists, and physicians should expose the fragile status of the factoid emphatically by highlighting its unreliable provenance and its lack of validity today, noting the many changes in e-cigarette devices and liquids, the accumulation of evidence of potential harm, the increased prevalence of use, and the growing evidence that e-cigarette use is associated with subsequent cigarette smoking. AJPH

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CONFLICTS OF INTERESTS

T. Eissenberg and A. Shihadeh are paid consultants in litigation against the tobacco industry and are named on a patent for a device that measures the puffing behavior of electronic cigarette users. In addition, as of September 2019, T. Eissenberg is a consultant in litigation against the electronic cigarette industry. S. Jordt reports receiving personal fees from Hydra Biosciences LLC and Sanofi SA and non-financial support from GlaxoSmithKline Pharmaceuticals outside the submitted work.

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An often-made claim that e-cigarettes are '95% safer' is not valid

Thomas Eissenberg of the Center for the Study of Tobacco Products at VCU was one of six experts who investigated the claim and found it unreliable and outdated

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https://www.eurekalert.org/pub_releases/2020-01/vcu-aoc010820.php

The frequently cited claim that e-cigarettes are "95% less risky" or "95% less harmful" than combustible cigarettes is outdated, misleading and invalid -- and should no longer be made in discussions on the dangers of vaping, according to an editorial published today in the American Journal of Public Health by six leading experts on e-cigarettes and public health.

"The '95% safer' estimate is a 'factoid': unreliable information repeated so often that it becomes accepted as fact," wrote the authors, including <u>Thomas Eissenberg</u>, <u>Ph.D.</u>, co-director of the <u>Center for the Study of Tobacco Products</u> at Virginia Commonwealth University.

"Public health practitioners, scientists, and physicians should expose the fragile status of the factoid emphatically by highlighting its unreliable provenance and its lack of validity today, noting the many changes in e-cigarette devices and liquids, the accumulation of evidence of potential harm, the increased prevalence of use, and the growing evidence that e-cigarette use is associated with subsequent cigarette smoking," they wrote.

The editorial, "Invalidity of an Oft-Cited Estimate of the Relative Harms of Electronic Cigarettes," re-examines the "95% safer" claim that originated in July 2013 when a group of experts in decision science, medicine, pharmacology, psychology, public health policy and toxicology rated the relative harm of 12 nicotine-containing products by using 14 criteria addressing harms to self and others. They concluded that combustible cigarettes were the most harmful and that electronic nicotine delivery systems were substantially less harmful.

However, the experts acknowledged that their study lacked hard evidence for the harms of most products it was evaluating. Despite that lack of evidence, the claim that e-cigarettes are "95% less risky" or "95% less harmful" was widely publicized, notably by Public Health England and the Royal College of Physicians.

Since then, Eissenberg and his co-authors wrote, a considerable amount of evidence of the potential harms of e-cigarettes has accumulated.

E-cigarette devices have changed significantly since the original study, they wrote, so much so that even if the original estimate was valid in 2013, it can no longer apply.

"For example, in addition to using different materials and more numerous heating coils, many ecigarettes today can attain power output that exceeds that of most over-the-counter 2013 models by 10 to 20 times (i.e., up to and sometimes exceeding 200 watts)," they wrote. "Greater power increases the potential harms of e-cigarette use because more aerosol is produced that exposes users to increased levels of nicotine and other toxicants."

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E-liquids also have changed since 2013, with widespread availability of thousands of flavors that use chemicals "generally recognized as safe" to eat but with unknown pulmonary toxicity, they wrote.

One particularly notable change has been the pervasive marketing of liquids with protonated nicotine, also known as "nicotine salt," which is made by adding an acid to free-base nicotine. Aerosolized protonated liquid is less aversive to inhale than free-base nicotine, thereby allowing users to increase the nicotine concentration of the liquid and likely increase their own nicotine dependence.

"Protonated nicotine e-cigarette liquids are available today in concentrations greater than 60 milligrams per milliliter, and these liquids have become very popular, sparking a 'nicotine arms race,'" they wrote.

Recent evidence also suggests that vaping harms users. One recent study cited in the article found that "[e-cigarette] aerosol constituents could injure the respiratory system or worsen preexisting lung disease through a variety of mechanisms." It also points to research associating wheezing, a symptom of potential respiratory disease, with e-cigarette use. And it notes that e-cigarette use has been shown to increase heart rate, blood pressure and platelet activation, and decrease flow-mediated dilation and heart rate variability, effects that suggest long-term cardiovascular risk.

The editorial also highlights research conducted since 2013 that found e-cigarette use is linked with a greater risk of the user starting to smoke combustible cigarettes.

Studies in the past six years also have shown that e-cigarette aerosol is not harmless, they wrote.

"For example, propylene glycol (PG) is one of the primary constituents of e-cigarette aerosol and is generally recognized as safe when eaten but, when injected intravenously over a period of days, is toxic," they wrote. "E-cigarette aerosols containing propylene glycol and vegetable glycerin, another common constituent, cause inflammation in human lungs, suggesting differing safety profiles for inhaled versus ingested propylene glycol and vegetable glycerin."

Along with Eissenberg, a professor in the VCU Department of Psychology in the College of Humanities and Science, the editorial was co-written by <u>Aruni Bhatnagar</u>, <u>Ph.D.</u>, of the American Heart Association Tobacco Regulation Center, University of Louisville; <u>Simon Chapman</u>, <u>Ph.D.</u>, of the School of Public Health, University of Sydney, Australia; <u>Sven Eric Jordt</u>, <u>Ph.D.</u>, of the Department of Anesthesiology, Duke University School of Medicine; <u>Alan Shihadeh</u>, <u>Sc.D.</u>, of the Maroun Semaan Faculty of Engineering and Architecture, American University of Beirut in Lebanon; and <u>Eric K. Soule</u>, <u>Ph.D.</u>, of the Department of Health Education and Promotion, East Carolina University.

Eissenberg and his colleagues were inspired to write the editorial after hearing report after report at the annual meeting of the Society for Research on Nicotine and Tobacco on the risks associated with e-cigarette use.

"It just occurred to me that with all these pieces of evidence, that we needed perhaps to revisit this '95% safer' claim to see whether it still had any validity today," Eissenberg said. "We all agreed that this was something that we really needed to do. We wanted people to take a look at the number and decide for themselves."

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It's important to understand the "95% safer" claim is bogus, he said, because it continues to be cited as a reason to start or continue vaping.

"People are using that claim as a reason to either keep using e-cigarettes if they started some time ago, or if they're nicotine-naive -- if they've never used nicotine before -- they hear 95% safer than combustible cigarettes and they say, 'Well, that's safe enough for me.' And so then they started using," he said.

The editorial's biggest takeaway, Eissenberg said, is that we simply do not know the long-term risks of e-cigarette use.

"It doesn't make any sense for us to claim that we know that it's 95% safer than combustible cigarettes," he said. "The fact is: we don't know whether e-cigarette use is as lethal as combustible cigarette use, less lethal than combustible cigarette use, or more lethal than combustible cigarette use.

"You have to understand: We've been studying combustible cigarettes for the last 60 to 70 years. And so we have a huge database with which we can look at how many people die from that behavior," he continued. "We don't have anything near that kind of history with electronic cigarettes. What we do know is that they are delivering toxicants to the human lung and that over repeated use, in some cases, we see health effects from those toxicants that e-cigarette users are inhaling."

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